

Eli Lilly & Co. v. Medtronic, Inc.: A Case of Statutory Interpretation

I. INTRODUCTION

To some, few topics are more relevant to legal craft and education than the interpretation of statutes, now our primary source of the law.¹ To others, the advent of post-New Deal agencies responsible for interpreting the statutes they are charged with enforcing has contributed to judicial ambivalence, when courts found their traditional interpretative functions usurped.² Few, however, see this everyday task resting on a solid framework.³ Indeed, the interpretation of statutes has remained a rather ad hoc enterprise, with basic rules of the game not fairly settled.⁴

The recently decided case of *Eli Lilly & Co. v. Medtronic, Inc.*⁵ is no exception. The Court's crucial job in *Lilly* was to properly interpret a recently enacted patent law that addressed drug developers' and drug competitors' rights. The arena was high-tech, the financial impact of the decision was substantial, and the ramifications on public health were potentially far-reaching.⁶ Thus, *Lilly* epitomizes the types of cases our courts are likely to hear as technology advances, but its analysis demonstrates both the danger of a court's misunderstanding high-technology issues and a misapplication of even its own stated principles of statutory interpretation.

The statute at issue in *Lilly* is 35 U.S.C. section 271(e)(1) ("section 271(e)(1)"), which reads:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913). . .) solely for uses reasonably related to the development and submission of information under a Federal law which

¹ William N. Eskridge, Jr. & Phillip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 STAN. L. REV. 321 (1990).

² Kenneth W. Starr, *Of Forests and Trees: Structuralism in the Interpretation of Statutes*, 56 GEO. WASH. L. REV. 703 (1988).

³ See Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 411-12 (1989).

⁴ Starr, *supra* note 2, at 704.

⁵ 110 S. Ct. 2683 (1990).

⁶ To illustrate the commercial importance in just this isolated case, the district court, upon finding that Lilly's patents were infringed, ordered Medtronic to pay damages of \$26,666,000. *Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033, 1040-41 (E.D. Pa. 1988).

regulates the manufacture, use, or sale of drugs or veterinary biological products.

This legislation, the Drug Price Competition and Patent Term Restoration Act of 1984 ("1984 Act"),⁷ was designed to simplify and expedite the availability of generic drugs while simultaneously encouraging pharmaceutical innovation simply by firming up the seventeen-year grant of patent protection for drugs and medical devices.⁸ Prior to the 1984 Act, the extensive testing procedures required by the United States Food and Drug Administration (FDA) substantially impeded the ability of both initial brand-name manufacturers and subsequent generic manufacturers to sell their drugs. The brand-name makers were hindered at the start of the patent period because the FDA-mandated multi-year clinical trials significantly cut into the precious seventeen-year patent period, thereby reducing the effective patent term. Generic drug makers were hindered at the end of this seventeen-year period because they could not start selling the now "free-market" drug until they too completed testing for the FDA.⁹ Further, a then-recent Federal Circuit Court decision refused to allow intrusion into this patent protection absent explicit approval by Congress.¹⁰

Congress partially alleviated this FDA testing impediment to drug sales through companion sections of the 1984 Act. First, Title II enabled initial brand-name drug developers to extend, in certain circumstances, their seventeen-year patent term to compensate for some of the years lost to FDA testing at the beginning of the patent term.¹¹ Second, Titles I and II of the 1984 Act enabled subsequent generic manufacturers to commence immediate drug sales as soon as the initial maker's patent expires by (1) shortening the FDA approval procedures for generic drugs and (2) permitting subsequent manufacturers to conduct their FDA testing during the protected patent term.¹² This is known as the exception-to-patent-infringement-for-FDA-testing provision.

⁷ Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of 21 and 35 U.S.C.).

⁸ See *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404-06 (Fed. Cir. 1989); see also Brian L. Strom, *Generic Substitution Revisited*, NEW ENG. J. MED. Vol. 316 No. 23, at 1456 (June 4, 1987).

⁹ *Lilly*, 872 F.2d at 404-05.

¹⁰ *Roche Prod., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984).

¹¹ Pub. L. No. 98-417, 201, 98 Stat. 1598 (1984) (codified in 35 U.S.C. § 156 (1988)).

¹² Pub. L. No. 98-417, § 101, 201, 98 Stat. at 1585, 1603, (1984) (codified in 21 U.S.C. § 355(j)(2)(A) and 35 U.S.C. § 271(e)(i) (1988)).

These procedural improvements in getting both initial and generic drugs to the market were presumably welcomed by consumers, but also by portions of the medical device industry who saw a way to use the new law to get their devices on the market quicker. Title II, the portion of the 1984 Act extending the patent term, applied these benefits to numerous "products," specifically, drugs, medical devices, food colors, food additives and other items addressed in the Food, Drug, and Cosmetic Act (FDCA).¹³ Title I, the exception-to-infringement-for-FDA-testing portion of the 1984 Act, however, did not specifically grant these benefits to all of the above products. Instead, Title II applied only to "patented invention(s) . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of *drugs*."¹⁴ Therefore, the question to be resolved was whether Title I of the 1984 Act applied to just drugs, or all Title II "products" such as medical devices, food additives, and food colors covered by the broad FDCA.¹⁵

The answer to this question became determinative in 1983 when Medtronic, Inc. began using Eli Lilly & Co.'s patented cardiac defibrillator for FDA premarket testing.¹⁶ Eli Lilly & Co. ("Lilly") claimed that Medtronic blatantly infringed on Lilly's defibrillator patents, set to expire in 1990 and 1993.¹⁷ Medtronic claimed that its use of the patented medical device was permitted under section 271(e)(1), the codification of Title I and the exception-to-infringement-for-FDA-testing provision, because this provision applied to medical devices as well as drugs.¹⁸ The District Court disagreed with Medtronic, stating that the clear language of section 271(e)(1) gave the exception-to-infringement-for-FDA-testing protection only to drugs, and issued a permanent injunction against Medtronic's use of Lilly's patented defibrillator.¹⁹ The Court of Appeals reversed, reasoning that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation."²⁰ Lilly appealed to the Supreme Court, which

¹³ 35 U.S.C. § 156(f) (1988).

¹⁴ 35 U.S.C. § 271(e)(1) (1988) (emphasis added).

¹⁵ Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301-93 (1988).

¹⁶ Brief for Petitioner, at 7 n.5, *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S.Ct. 2683 (1989), (No. 89-243).

¹⁷ *Lilly*, 110 S.Ct. at 2685.

¹⁸ *Id.*

¹⁹ *Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033 (E.D. Pa. 1988).

²⁰ *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

agreed with the Court of Appeals, and found that the "natural sense" and the "structure of the 1984 Act as a whole"²¹ could give no other result.

A persuasive reason does exist, however, why Congress should choose to distinguish drug patent activities from medical device patent activities; namely, because the FDA's regulatory scheme is significantly different for drugs than for medical devices and these FDA regulations significantly dictate a drug or medical device's patent life. Thus, both the structure and clear language of the legislation can support a congressional intent to apply section 271(e)(1) to drugs alone. The FDA's regulatory scheme and its effects on drugs and medical devices at the beginning and end of their patent lives is the topic of Part II of this Comment. Part III will explore the basic tenets of statutory interpretation, and Part IV will re-examine the *Lilly* opinion. Finally, this Comment will conclude that, had the Court been either fully aware of the drug-device distinction or followed basic principles of statutory interpretation, the *Lilly* outcome would have been different.

II. THE REGULATORY DIFFERENCES AFFECTING DRUG AND MEDICAL DEVICE PATENT LIVES

A. Drug and Medical Device Regulation

Partially in response to Upton Sinclair's shocking book *The Jungle*,²² describing the filthy meat-packing conditions in Chicago, Congress first authorized the regulation of food and drugs under the Pure Food and Drug Act of 1906.²³ To further this primary goal of ensuring safety, Congress substantially expanded food and drug regulation in 1938 with the FDCA.²⁴ But it was not until 1962 when the FDA began testing for efficacy as well as safety that medical devices became subject to regulations under the FDCA.²⁵

The Medical Device Amendments of 1976 ("1976 Amendments") to the FDCA commenced the extensive federal regulation of medical devices.²⁶ The 1976 Amendments permitted the FDA to classify a medical

²¹ *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2688 (1990).

²² UPTON SINCLAIR, *THE JUNGLE* (1965).

²³ Ann Myers & Steven R. Moore, *The Drug Approval Process and the Information It Provides*, 21 *DRUG INTELLIGENCE AND CLINICAL PHARMACY* 821 (1987).

²⁴ *Id.*

²⁵ *Id.*

²⁶ Jonathan S. Kahan & Jeffrey N. Gibbs, *Food and Drug Administration Regulation of Medical Device Biotechnology, and Food and Food Additive Biotechnology*, 11 *APPLIED BIOCHEMISTRY AND BIOTECHNOLOGY* 507, 508 (1985).

device depending upon the degree of risk it posed, and to demand clinical testing of a small percentage of devices during the premarket approval process.²⁷ Class I medical devices pose little risk to health and include items such as bedpans, tongue depressors, crutches, and stethoscopes. Therefore, these are subject only to general manufacturing controls and not human clinical testing.²⁸ Class II devices constitute the bulk of medical devices, and include devices such as heating pads and fetal monitors.²⁹ Only the Class III devices like cardiac pacemakers and defibrillators, because they are intended for use in life-supporting or life-sustaining circumstances or present an unreasonable risk of illness or injury, are subject to the FDA's premarket approval process and mandatory human clinical testing.³⁰

Under section 510(k) of the 1976 Amendments, new medical devices are automatically categorized as Class III devices unless they are substantially equivalent to either a Class I or II device, or a pre-1976 Amendments device.³¹ As a first step in categorizing a new medical device, all potential manufacturers are required to provide the FDA with a ninety-day notice before a new or modified medical device may be marketed. If the FDA, after reviewing the device, determines that it is not substantially equivalent to a pre-1976 Amendments device, the agency will advise the manufacturer that its device is indeed a Class III medical device and request that an appropriate premarket approval procedure be completed by the manufacturer. Such approval procedures include filing a premarket approval application (PMA), a product development protocol (PDP), or a request for reclassification to a Class I or II device.³² The PMA the FDA requires of Class III devices is similar to that required for new drugs, namely extensive clinical testing on many hundreds to thousands of patients.³³ The number of devices that must proceed through this premarket approval process is relatively and remarkably small. In 1985, out of the 5200 devices submitted to the FDA for approval, only ninety-five required such clinical testing.³⁴ Additionally, the waiting period for ultimate FDA approval is relatively short. In 1985, device makers spent approximately

²⁷ *Id.*

²⁸ *Id.*

²⁹ Vincent Brannigan, *The Regulation of Medical Expert Computer Software as a "Device" Under the Food, Drug, and Cosmetic Act*, 27 JURIMETRICS J. 370, 372 (1987).

³⁰ Kahan & Gibbs, *supra* note 26, at 508.

³¹ *Id.*

³² *Id.* at 509.

³³ *Id.* at 508.

³⁴ *Id.* at 515 n.7.

two to four years conducting the actual clinical testing, and then an average of eleven and one-half months waiting for FDA approval.³⁵

In contrast is the regulatory scheme for drugs. In order to market a drug, all manufacturers of a new drug must submit to the FDA a New Drug Application (NDA) containing the results of the manufacturer's clinical trials.³⁶ Clinical trials are the series of tests using the drug in humans and on average requires two to twelve years to complete.³⁷ All of the testing is conducted after the manufacturer obtains his patent.³⁸ The final phase of clinical trials, Phase III, is when the most extensive testing occurs.³⁹ Here the manufacturer assesses the safety, effectiveness, and most desirable dosage of the drug in treating a specific disease in a large group of patients—usually several hundred to several thousand, depending on the drug.⁴⁰

The creation of generic drugs and the generic drug industry, however, has changed the need for these extensive clinical trials. Generic drugs, which are exact chemical replicas of the active ingredients in brand-name drugs,⁴¹ do not need to survive such rigorous tests, presumably because the safety and efficacy testing has already been done by the original maker when he initially applied to market the drug. To require a second maker to

³⁵ See Edward M. Basile, *Improving FDA's Product Approval Process for Medical Devices*, 41 FOOD DRUG & COSM. L.J., 287, 288-89 (1986).

³⁶ 21 U.S.C. § 355 (1988); see also Requirements of Laws and Regulations Enforced By the U.S. Food and Drug Administration, HHS Pub. No. (FDA) 85-1115 at 40. Actually, the drug approval process is more complex than this and does not start with an NDA. Prior to the filing of an NDA, a sponsor, who is usually but not necessarily always the manufacturer, files an investigational new drug (IND) application which provides preliminary information such as descriptive name of the drug and the route of administration, complete list of components, quantitative composition, source of the new drug, chemical and manufacturing information, preclinical test results (any clinical studies or experience), clinical protocol, scientific training and experience of investigators, statements to the effect that the sponsor will notify the FDA when and if studies have been discontinued, notice that an institutional board will be responsible for continuing review of the proposed study, and results of any and all animal studies that were conducted prior to submitting the IND in order to document that the drug should be safe in humans and not impose an unreasonable risk. See Myers & Moore, *supra* note 23, at 821.

³⁷ See A. Alister Dunning, *Regulation, New Drug Development, and the Question of Delay*, 41 FOOD DRUG & COSM. L.J. 139, 140-41 (1986).

³⁸ See Myers & Moore, *supra* note 23, at 823. Also, as a practical matter, one would not wish to share his new invention with the rest of the world, even for conducting clinical testing, without patent protection.

³⁹ *Id.* at 822.

⁴⁰ *Id.*

⁴¹ Defined in 21 U.S.C. § 355(j)(7)(B) (1988).

repeat these same tests would be a meaningless expense of time and money, and an unreasonable delay in getting the generic drug to the consumer. Therefore, Title I of the 1984 Act created a truncated procedure for manufacturers of generic drugs desiring FDA approval, rather appropriately named the Abbreviated New Drug Application (ANDA).⁴² Under this procedure, a potential generic drug manufacturer need only demonstrate the bioequivalence of his drug to the original or pioneer drug.⁴³ In other words, a generic drug manufacturer now must prove only that his drug is similarly absorbed and reaches the similar concentrations in a person's blood as the original manufacturer's drug.⁴⁴ This bioequivalency testing can be done on a significantly smaller group of normal, healthy volunteers and therefore takes far less time and money to complete than a full NDA.⁴⁵

The current differences between drug and medical device regulation must be considered before any attempt is made to analyze either a holistic scheme of regulation or a legislative history package. While it normally would make no difference whatsoever in an average textual analysis because the text only is examined, it would have in the *Lilly* case because, paraphrasing the majority, "[t]his statute has no plain meaning to me because I can't imagine why anyone would want it to mean what it says on its face."⁴⁶

B. Differences in Regulation

As the preceding discussion indicates, one obvious difference between drugs and medical devices is that all drugs are subject to significant testing

⁴² 21 U.S.C. § 355(j) (1988); 21 C.F.R. § 314.56 (1991).

⁴³ See *United States v. Undetermined Quantity of an Article of Drug*, 709 F. Supp. 511, 515 (D.N.J. 1987) (discussing 21 U.S.C. § 355(j), which established the ANDA for "drug products that are closely related to previously approved products").

⁴⁴ *Id.*; see also *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2692 (1990).

⁴⁵ *Lilly*, 110 S.Ct. at 2695, describing the abbreviated procedure. "These procedures, in general, do not affect the market in a substantial manner because manufacturers may test the drug on a small number of subjects, who may include healthy persons who would otherwise not buy the drug." *Id.*; see 35 U.S.C. § 355 (j)(7)(B) (1988) (stating the requirements of a showing of the "bioequivalence" of drugs).

⁴⁶ See *Lilly*, 110 S.Ct. at 2690:

It seems most implausible to us that Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements in this entire area . . . should choose to address both those distortions only for drug products It would take strong evidence to persuade us that this is not what Congress wrought, and there is no such evidence here.

for safety and effectiveness, while all devices are not.⁴⁷ Specifically, all drugs are subject to bioequivalence testing before the first dose can be sold to a consumer, even generic drugs that are chemically identical to already marketed drugs.⁴⁸ Devices are not.⁴⁹ To the contrary, under section 510(k) of the 1976 Amendments, device manufacturers are required to give the FDA only a ninety-day notice before a new or modified device may be marketed.⁵⁰ Only if the potential manufacturer cannot convince the FDA that its device should be a Class I or II medical device does the FDA actually require premarket approval procedures.⁵¹ Then and only then must the medical device undergo the relatively expensive clinical trials, similar to an NDA for new drugs.⁵²

It is vitally important to recognize the impact that these premarket approval procedures have on the effective length of a drug or device patent.⁵³ For a device that needs no clinical testing prior to marketing, as ninety-eight percent do not, the patent life is basically unaffected. An original manufacturer can begin selling its device right at the start of its seventeen-year grant of patent protection, and a subsequent manufacturer can start selling the device as soon as the seventeen-year term has expired. Only an original manufacturer with a life-sustaining Class III medical device, which accounts for less than two percent of the new devices sold every year, must complete the extensive clinical trials similar to the trials that a new drug manufacturer must complete.⁵⁴ A drug manufacturer must, however, *always* complete clinical testing for the FDA. The extent of the clinical testing depends on whether it is a new drug manufacturer or a

⁴⁷ The testing for drugs has to be done by somebody, usually the original drug maker. *See supra* notes 35–39 and accompanying text. In contrast, 5100 out of 5200 medical devices need no premarket approval. *See supra* note 33 and accompanying text.

⁴⁸ *See supra* notes 40–44 and accompanying text; *Eli Lilly*, 110 S.Ct. at 2695 (“[M]anufacturers may test generic versions of patented drugs, but not devices, under abbreviated procedures.”).

⁴⁹ *See supra* notes 27–34 and accompanying text.

⁵⁰ *See supra* notes 30–31 and accompanying text.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *See Eli Lilly & Co., v. Medtronic, Inc.*, 110 S. Ct. 2683, 2695 (1990) (“Testing a patented medical device, however, often will have greater effects on the patent holder’s rights than comparable testing of a patented drug. . . [because the abbreviated procedures available to the generic drug industry] do not affect the market in a substantial manner because manufacturers may test the drugs on a small number of subjects, who may include healthy persons who would not otherwise buy the drug.”)

⁵⁴ *See supra* note 33 and accompanying text.

subsequent generic manufacturer and it files the required NDA or ANDA, respectively.⁵⁵

Also note the effect that clinical testing during the patent period has on the market for the drug or device: the smaller the market for a particular drug or device, any intrusion into the market, even for allegedly benign clinical testing, strips the patent owner of a sale. Because Class III medical devices are, by definition, for life-sustaining treatment, they tend to be high-technology products with small markets. For example, if a subsequent cardiac defibrillator manufacturer estimates that its clinical testing should take five years and therefore starts its clinical testing twelve years into the life of the original manufacturer's seventeen-year patent, even for the legitimate purpose of gathering data to submit to the FDA at the end of the seventeen-year patent term, it would necessarily use patients in its tests who otherwise would have bought the patent owner's device.

Such a scenario is especially likely in the high-technology fields such as cardiac defibrillating. There simply is not an unlimited supply of people who need to use a cardiac defibrillator, and for every patient that the subsequent device maker "uses" for testing, the patent holder is denied a sale.

This same scenario does not hold true for a subsequent generic cardiac drug manufacturer because it does not need to use an actual cardiac patient to test its drug. Instead, it has the ANDA procedures to follow in which only bioequivalence of the drug in normal, healthy volunteers needs to be demonstrated.⁵⁶ Thus, its clinical testing does not strip a patient and thus a sale away from the patented drug owner.

It is the appropriate time to re-examine section 271(e)(1), a 1984 statute that states that it is no longer patent infringement to use a "patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates . . . drugs."⁵⁷

III. STATUTORY INTERPRETATION

As previously stated, the task of statutory interpretation, although a routine chore, unfortunately does not rest on a solid framework.⁵⁸ Despite questionable consensus about the proper means of interpretation, however, some conventions predominate and are generally accepted today in the legal

⁵⁵ See *supra* notes 35–44 and accompanying text.

⁵⁶ See *supra* notes 40–42, 52 and accompanying text.

⁵⁷ See *supra* note 8 and preceding text.

⁵⁸ See Sunstein, *supra* note 3.

profession.⁵⁹ The first convention is that when interpreting a statute, one starts with the statute itself. "Interpretation of a statute must begin with the statute's language,"⁶⁰ and only after will it move to matters extrinsic to the statute, such as legislative history and social policy. In other words, courts will look first to the text of the statute, and if a plain meaning is identifiable, the court will not permit itself to review any extrinsic sources.⁶¹ If, however, the language is unclear, then and only then will the court look to matters extrinsic to the statute for evidence of the legislature's intent.⁶²

Traditionally the first step in statutory construction was to look at the text for the "plain meaning" of the statutory language.⁶³ Even today, those who enjoy the task of statutory interpretation believe that judges ought to look at the "plain meaning" doctrine not as a set of handcuffs, but as the given first rule of our interplay with the legislative branch.⁶⁴ Indeed, textualism appears to be enjoying a renaissance in a number of recent cases, and perhaps in academia as well.⁶⁵

There are, however, scholars who disagree. Some believe that the textual approach is too simple to give an answer in any but the most elementary cases.⁶⁶ Some extend their criticisms of the rule to say that, even if courts could accurately interpret a statute's plain meaning, they

⁵⁹ Peter S. Schanck, *The Only Game in Town: An Introduction to Interpretive Theory, Statutory Construction, and Legislative Histories*, 38 KAN. L. REV. 815, 818 (1990). But see Sunstein, *supra* note 3, at 414 ("In the conventional account, the tools of statutory construction are language, structure, and history. . . . Each, however, is flawed.")

⁶⁰ *Mallard v. United States*, 490 U.S. 296, 300 (1989).

⁶¹ Schanck, *supra* note 59, at 818.

⁶² *Id.*; see also 2A NORMAN J. SINGER, SUTHERLAND'S STATUTES AND STATUTORY CONSTRUCTION §§ 46.01, 45.02 (C. Sands 4th ed. 1984).

⁶³ Schanck, *supra* note 59, at 818; see also 3A SUTHERLAND'S, at 681 ("The canon of plain meaning is the starting point for most problems of statutory interpretation.")

⁶⁴ Abner J. Mikva, *Statutory Interpretation: Getting the Law To Be Less Common*, 50 OHIO ST. L.J. 979, 981 (1989); see also *Exchange Nat'l Bank v. Touche Ross & Co.*, 544 F.2d 1126, 1138 (2nd Cir. 1976) (Friendly, J.) ("courts had better not depart from their [statutes'] words without strong support for the conviction . . . they are doing what Congress wanted when they refuse to do what it said"); Frank H. Easterbrook, *Statutes' Domains*, 50 U. CHI. L. REV. 533, 544-51 (1983).

⁶⁵ Sunstein, *supra* note 3, at 416.

⁶⁶ *Id.* at 423; see also STANLEY FISH, *DOING WHAT COMES NATURALLY* 87-102 (1989); ROBERTA M. UNGER, *KNOWLEDGE AND POLITICS* 88-100 (1975).

should not rely solely on this because often Congress did not actually intend this anyway.⁶⁷

Applying this textual approach requires two additional rules of statutory interpretation; applying appropriate definitions and giving effect to all parts of the statute.⁶⁸ Clearly, the plain meaning depends upon the definitions of the words being interpreted. Also, any plain meaning cannot ignore a part of the statute at hand.

A. *The Decision Applying Traditional Interpretive Principles*

In applying this first step of statutory interpretation to the *Lilly* case, Eli Lilly & Co. argues that the plain reading of the statutory language of section 271(e)(1) grants a narrow exemption from patent infringement for developing information necessary to obtain approval for “drugs” and “veterinary biological products,” the specifically enumerated categories.⁶⁹ Medtronic asserts that “drugs” and “veterinary biological products” are not the types of inventions that receive noninfringement protection, but rather are descriptive terms for the type of federal law requiring the submission of information. Thus, using Medtronic’s rationale, “a Federal law which regulates the manufacture, use, or sale of drugs” is shorthand for *all* the provisions of the landmark 1938 Federal Food, Drug, and Cosmetic Act. Because this law also regulates medical devices, Medtronic asserts that their medical device testing should receive the benefit of the exception-to-infringement section 271(e)(1).⁷⁰

Apparently, both parties ignore vital statutory language in the contested sentence of the statute. The statute itself defines the terms being used: “as those terms [that] are used in the Federal Food, Drug, and Cosmetic Act.”⁷¹ Clearly, when the same sentence of a statute explicitly directs a certain definition, the plain meaning of the statute requires that the reader use the supplied definition.⁷²

⁶⁷ Sunstein, *supra* note 3, at 424.

⁶⁸ A textual approach, because it concerns itself with the text, can be considered synonymous with what others have referred to as intrinsic aids to statutory interpretation; namely, deriving meaning from the internal structure of the text and conventional or dictionary meanings. *See* SINGER, *supra* note 62, at § 45.14.

⁶⁹ Brief for Petitioner at 21, *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S.Ct. 2683 (1989) (No. 89-243).

⁷⁰ Brief for Respondent at 6-7, *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S.Ct. 2683 (1989) (No. 89-243).

⁷¹ 35 U.S.C. § 156(f)(2) (1988).

⁷² An argument can be made that because the definitional reference is in the middle of the statutory sentence, it is not a definitional reference for the entire sentence of the statute. As stated in Sutherland’s on Statutory Construction, however:

Looking at the FDCA for the definition of "drugs," one finds that medical devices are expressly excluded from the definition of the term "drug."⁷³ Further, foods are expressly excluded from the definition of a "drug."⁷⁴ Therefore, the statute implicitly reads "under a Federal law which regulates the sale of drugs, excluding medical devices and foods." It should be obvious to even a casual observer that the statute's plain meaning specifically excludes from its application those laws that regulate medical devices and foods. Accordingly, Medtronic's assertion that section 271(e)(1) refers to the entirety of the FDCA, the broad federal law regulating various products including foods, drugs, and medical devices, is contrary to the most plausible reading of the statute. Once the appropriate definitions are utilized, it becomes clear that the statute refers to those portions of the law which regulate only drugs.

Unfortunately, though, neither the Supreme Court nor the court of appeals read the statute in this manner. Instead, they chose to ignore this

It is not unusual for statutes to contain definition[s] of the terms used in them. . . . It is commonly understood that such definitions establish meaning where the terms appear in the same act or in the case of general interpretive statutes, the definition extends to as much legislation as the general act itself designates.

SINGER, *supra* note 62, at § 47.07. And further,

If it is expected that a particular term would be defined in the body of the statute, but is not, then the word will be assumed to have its ordinary and popularly understood meaning. If words are used that have a definite and well-known common-law meaning, that meaning will be used unless a contrary intent appears.

Id. § 47.07 (Supp. 1991).

Therefore, the statute's reference to "as those terms are used in the Federal Food, Drug, and Cosmetic Act" should provide the correct definitional reference. If, however, one would argue that it does not, then the term "drug" would have an ordinary meaning. Such ordinary meaning of "drug" excludes medical devices. *See* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 695 (1961).

⁷³ *See* 21 U.S.C. § 321(g)(1) (1988) ("The term 'drug' . . . does not include devices or their components, parts, or accessories."). *Cf.* 21 U.S.C. § 355 (1988) (drug regulation) and 21 U.S.C. § 360 (1988) (device regulation).

⁷⁴ *See* 21 U.S.C. § 321(g)(1) (1988) (defining drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."); *see also* Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration, HHS Pub. No. (FDA) 85-1115 at 40.

plain meaning and instead focus on what they perceived to be the intended purpose. To the court of appeals, the purpose of the 1984 Act was to overrule *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,⁷⁵ the 1984 decision that refused to create an exception-for-infringement-for-FDA-testing for either drugs or medical devices.⁷⁶ Because the *Roche* court stated that Congress was the appropriate forum to resolve such matters, this court reasoned that any subsequent legislation must necessarily be meant to overrule *Roche*.⁷⁷ The Supreme Court took a different avenue, stating that while the statute "more naturally reads" as the court of appeals determined, the text of section 271(e)(1) is "not plainly comprehensible on anyone's view."⁷⁸ It is quite interesting to note the divergent paths that each of these respected courts took once the crucial first step of reading the statute was dismissed.

B. *The Decision as It Stands*

As Justice Scalia states in the majority opinion:

The core of the present controversy is that petitioner interprets the statutory phrase, "a Federal law which regulates the manufacture, use or sale of drugs," to refer only to those individual provisions of federal law that regulate drugs, whereas respondent interprets it to refer to the entirety of any Act (including, of course, the FDCA) at least some of whose provisions regulate drugs.⁷⁹

Using the established conventions of statutory interpretation, the Court begins its analysis with "the basis of words alone."⁸⁰ One assumes this is shorthand for the plain meaning rule, or a textual approach. Applying this rule to the statute at issue, namely, section 271(e)(1), the Court examines the phrase "a Federal law." Admitting that the phrase could be used to denote either a portion of a statute or an entire act, the Court determines that the phrase probably refers to the latter because it "more naturally summons up the image of an entire statutory scheme of regulation."⁸¹ The Court bases this conclusion on three aspects of statutory interpretation having nothing to do with the plain meaning rule: better ways for Congress

⁷⁵ *Roche Prod., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert denied*, 469 U.S. 856 (1984).

⁷⁶ *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405 (Fed. Cir. 1989).

⁷⁷ *Id.*

⁷⁸ *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S.Ct. at 2683, 2688 (1990).

⁷⁹ *Id.* at 2686.

⁸⁰ *Id.*

⁸¹ *Id.* at 2687.

to refer to a statutory portion, the "common" way to speak, and reference to different portions of the entire 1984 Act, an act other than the one at issue.⁸²

The Court then continues the "textual" analysis by looking at the reasons anyone could have for making such a distinction the touchstone of infringement. The Court finally concludes that, while the respondent has a more plausible reading of the statute, the statute is not plainly comprehensible in anyone's view.⁸³

Immediately, there are several problems with the such an analysis. First, the Court examines only one phrase of one sentence in the statute before it. The Court makes no mention of the remainder of the statute. Perhaps further errors could have been eliminated if the Court had indeed looked at the entire statute that the respondent brought into question, that is, section 271(e)(1). Also, the Court used methods in applying its textual approach that it previously had expressly forbidden; namely, it approached the interpretive question from behind and asked what Congress should or could have written. As the *Lilly* dissent points out, the Court has stated that they are not to tell Congress how to write its laws.⁸⁴

Admittedly, the Court does not rest its ultimate conclusion on this analysis. The Court does, however, use this "better way" approach to invalidate the plain meaning of the statute. Clearly this is a dangerous and significant departure from traditional interpretive principles if the Court is permitting the use of a "better" or more "common" way to speak as a means of nullifying an otherwise plain meaning.

Moreover, the Court hypothesizes under an allegedly textual approach the possible purposes Congress might have for wanting the statute to mean what the statute most naturally says. Because the Court can find no plausible reason for why "anyone would want it to mean that,"⁸⁵ the Court concludes that what it perceives to be the "more natural meaning"⁸⁶ must not be the plain meaning. Therefore, the Court says, the statute is "not plainly comprehensible on anyone's view."⁸⁷

Note carefully what the Court has done. Because the Court cannot perceive a legitimate reason for anyone wanting to differentiate between drugs and medical devices in this patent area, it then presumes the patent statute cannot be making such a distinction. The Court does this despite the

⁸² *Id.* at 2687-88.

⁸³ *Id.* at 2688.

⁸⁴ *Id.* at 2694. Justice Kennedy writes "[t]he Court asserts that Congress could have specified this result in a clearer manner. *See ante*, at 2687-88. That is all too true. But we do not tell Congress how to express its intent."

⁸⁵ *Lilly*, 110 S.Ct. at 2687.

⁸⁶ *Id.* at 2688.

⁸⁷ *Id.*

fact that this is precisely what the statute says, using the definitions expressly pointed out in the specific statutory sentence itself.

Clearly, this method is not the proper application of the textual approach. The textual approach looks at, surprisingly enough, the text alone, and not alternative texts, extended texts, or the possible purposes of the text. These issues are extrinsic to any statute, and should be dealt with only after the textual analysis is employed.

Matters extrinsic to a statute can illuminate that which the text alone does not. Hopefully, the text as understood in light of the context and background of the statute will resolve ambiguities or fill gaps to give us the right answer, that is, what the legislators would have written had they been confronted with the problem at hand.⁸⁸ Legislative history, structure, purpose, and intent are the primary tools for this analysis.⁸⁹

The literature is replete with arguments both lauding and criticizing the use of legislative history in interpreting statutes.⁹⁰ Of particular interest is that prior to the *Lilly* decision the majority writer, Justice Scalia, had generally espoused great reliance on statutory text⁹¹ and had expressed considerable doubt about the use of legislative history in statutory interpretation.⁹² Scalia recognized that parts of the history may have been "composed" by one side or the other, and cautioned the courts not to accord weight to legislative history at the expense of statutory language.⁹³

In *Lilly*, Justice Scalia paid lip service to his prior views, stating that the legislative history in support of either party "sheds no clear light."⁹⁴ He employed, however, legislative history in the guise of another extrinsic tool—examination of the structure of an entire act—to interpret the statute.⁹⁵ To him it seemed probable that Congress would have considered the related parts of the statute, which addressed the distortion of patent protection because of lengthy regulatory approval requirements, as part of a single legislative package.⁹⁶ Moreover, because it seems "most implausible to us that Congress . . . should choose to address both those distortions only for drug products . . . [I]t would take strong evidence to persuade us that this is what Congress wrought. . . ."⁹⁷

⁸⁸ Sunstein, *supra* note 3, at 424.

⁸⁹ *Id.* at 425.

⁹⁰ Starr, *supra* note 2, at 705–06.

⁹¹ Sunstein, *supra* note 3, at 430.

⁹² *Id.* at 429.

⁹³ *Id.* at 431.

⁹⁴ *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S. Ct. 2683, 2688 (1990).

⁹⁵ Starr, *supra* note 2, at 709.

⁹⁶ *Lilly*, 110 S. Ct. at 2688 n.3.

⁹⁷ *Id.* at 2690.

Here again, the Court repeats its error: because it cannot imagine a reason for differentiating drugs from medical devices, it again rejects the idea that Congress meant to do just that.

IV. ANOTHER LOOK AT *ELI LILLY & CO. V. MEDTRONIC, INC.*

When Medtronic, Inc. first began using Eli Lilly & Co.'s patented cardiac defibrillator in 1983, section 271(e)(1) had not yet been enacted.⁹⁸ This fact, the trial court found, was evidence of willful infringement of the invention.⁹⁹ Therefore, the court granted Lilly the standard willful infringement remedies of treble damages and an injunction.¹⁰⁰

The subsequent courts did not agree with this result. Instead, the Supreme Court looked at section 271(e)(1) first "on the basis of words alone,"¹⁰¹ then on the basis of legislative history,¹⁰² and finally at the "structure of the 1984 Act as a whole."¹⁰³ Under each step of this analysis the Court should have found the statute provided no exception for infringement of medical devices. Under a textual analysis, the Court should have applied the definition explicitly referred to in the statute, which unequivocally states that drugs do not include medical devices, and ended the matter there.¹⁰⁴ But they did not. Next, the Court summarily dismissed legislative history as being inconclusive,¹⁰⁵ probably because of some of the Justices' own presumptions regarding the invalidity of legislative history.¹⁰⁶ Instead, the Court looked at the structure of the whole 1984 Act, not just section 271(e)(1), which was before it, and decided that it made no sense to distribute patent protections unequally.¹⁰⁷

The Court's repeated mistake was the inability to appreciate the difference between drugs and medical devices—the difference in their bundle of sticks, if you will—that Congress had attempted to preserve. If

⁹⁸ Brief for Petitioner at 7 n.5, *Eli Lilly & Co. v. Medtronic, Inc.*, 110 S. Ct. 2683 (1990) (No. 89-243).

⁹⁹ *Id.* at 8.

¹⁰⁰ *Lilly*, 110 S.Ct. at 2685.

¹⁰¹ *Id.* at 2686-88.

¹⁰² *Id.* at 2688.

¹⁰³ *Id.*

¹⁰⁴ This is also the approach of Justice Kennedy in the dissent: "I dissent because I find the Court's decision contrary to the most plausible reading of the statutory language." *Id.* at 2693. Also, "[w]hen § 271(e)(1) speaks of a law which regulates drugs, I think that it does not refer to particular enactments or implicate the regulation of anything other than drugs." *Id.*

¹⁰⁵ *Id.* at 2688.

¹⁰⁶ See *supra* notes 89-92 and accompanying text.

¹⁰⁷ *Lilly*, 110 S.Ct. at 2690.

the Court had appreciated the significance of this vital premarket approval difference and the necessary interplay between these procedures and the patent process, then it probably would have interpreted the statute differently.¹⁰⁸ The Court should have recognized the minimal premarket testing required for the great majority of devices¹⁰⁹ and, in comparison to the NDA's and ANDA's required for drugs,¹¹⁰ realized that Congress really could have meant what was said in section 271(e)(1). There is, contrary to the majority's opinion, a plain meaning that can be gleaned from the text of section 271(e)(1) exactly as written, namely that "a federal law which regulates drugs" excludes those that regulate medical devices because by the supplied definition, a drug is not a medical device. Further, if the Court chooses to examine either the legislative history or the entire structure of the 1984 Act, it should realize that Congress did not intend to let a subsequent device maker infringe on an original patent holder's right to exclusively use that device for seventeen years. This is because medical device testing, using patients for clinical testing who otherwise would be consumers buying devices from the patent holder, necessarily cuts into the finite market of the medical device owner, while ANDA testing does not because that testing requires only normal, healthy volunteers.¹¹¹

V. CONCLUSION

In *Lilly*, the Court dangerously extended the narrow congressional grant of an exception-to-patent-infringement-for-testing-purposes for drugs of section 271(e)(1) to allow willful infringement of medical devices. This danger was articulated by the court in *Roche*,¹¹² the very case that prompted Congress to create the narrow infringement exception, when they said that they would not allow such action without "explicit" approval from Congress.¹¹³ The *Roche* court must have recognized that any exceptions to patent infringement can substantially determine the route that medical research and development dollars follow. No economically rational company would make a decision to invest millions of dollars in inventing a

¹⁰⁸ The Court does indicate that it was aware of the premarket approval effect, but dismissed it for lack of relevance. "The centrally important distinction in this legislation (from the standpoint of commercial interests affected) is not between applications for drug approval and applications for device approval, but between patents relating to drugs and patents relating to devices." *Id.* at 2687.

¹⁰⁹ See *supra* note 33 and accompanying text.

¹¹⁰ See *supra* notes 35-44 and accompanying text.

¹¹¹ See *supra* note 52 and accompanying text.

¹¹² *Roche Prod., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

¹¹³ *Id.* at 867.

device only to allow a competitor to substantially take away its market during the seventeen-year grant of patent protection. In its Brief, Medtronic asserts that American research will relocate to foreign countries if an FDA-testing patent exemption is not available for devices.¹¹⁴ This argument is precisely contrary to the very purpose of our stringent patent laws, that is, to encourage entrepreneurial productive efforts by guaranteeing a seventeen-year monopoly for the inventor.¹¹⁵

The legislative history of section 271(e)(1) demonstrates that Congress considered these issues and decided that there is "no adverse economic impact on the patent owners's exclusivity during the life of the patent" due to bioequivalence testing of a patented drug product.¹¹⁶ Notably, however, Congress did not make identical statements about medical devices because the regulatory distinctions between drugs and medical devices would render such a statement false. Instead, Congress said:

Title I of the bill permits the filing of abbreviated new *drug* applications before a patent expires Title II permit[s] the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.¹¹⁷

In addition to discouraging inventions of medical devices and expanding section 271(e)(1) beyond its intended scope, the Court's interpretation of section 271(e)(1) furthers interpretive confusion. Under the guise of following established conventions of statutory interpretation, and even its own emerging brand, the Court apparently applied its own version of common sense at the first step, and thereby blinded itself to any real analysis of the statute. Thus, instead of providing concrete guidance in statutory interpretation, the Court has made laws more difficult for Congress to write, agencies to interpret, and citizens to follow.

Patricia Nussle

¹¹⁴ Brief for Respondent *Lilly*, 110 S.Ct. at 2683 (No. 89-243). At least some commentators agree with this rationale for patent approval of devices. *See also* Basile, *supra* note 35, at 290. After describing how new medical device technology is revolutionizing medical practice, Basile concludes that "[r]educing product approval delays should therefore be a top priority."

¹¹⁵ *See Lilly*, 110 S.Ct. at 2688.

¹¹⁶ Brief for Respondent at 24, *Lilly*, 110 S. Ct. at 2683 (No. 89-243).

¹¹⁷ H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 46 (1984) (emphasis added).